

## REMARKS

Applicants have amended the specification, as set forth above. No new matter has been added by way of these amendments. In view of these amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Claims 1-5, 7-11, 13, 16, 18-22, and 24-29 stand rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,494,863 to Shaw ("Shaw") in view of U.S. Patent No. 5,084,017 to Maffetone ("Maffetone"). This rejection is respectfully traversed.

In the Examiner's view, FIGS. 15-19 of Shaw describe a disabling system for a plunger comprising a plunger (handle 116) comprising a plurality of aligned steps (serrations 124) disposed longitudinally along the plunger (FIG. 15) and a collar having inner and outer members (clip structure 114 = outer member; collar 126 = inner member) mountable to the barrel (FIG. 15). Allegedly, the outer member has pawls (teeth 136) that are capable of engaging plunger ratchets (FIG. 18), the inner member operable to prevent engagement of the ratchets by the pawls until the plunger is depressed.

The Examiner concedes that Shaw does not teach one or more projections resiliently deformable to prevent initial engagement of the ratchets by the pawls until the plunger is depressed. However, the Examiner is of the view that Maffetone discloses a guide pin 85 which is resiliently deformable to prevent initial engagement of the ratchets by the pawls until the plunger is depressed. The Examiner submits that at the time of invention, it would have been obvious to one of ordinary skill in the art to modify the device of Shaw with the projection (guide pin, 85) of Maffetone to prevent premature movement of the actuating rod into the solution dispensing mode (Column 7, lines 38-50).

Applicants cannot agree with the Examiner's statement that guide pin 85 of Maffetone is "resiliently deformable". There is no explicit, implicit or inherent disclosure in Maffetone that would lead a skilled person to believe that guide pin 85 is resiliently deformable. As described at column 3 lines 42-49, the stationary guide pin is initially seated in guide track A. At column 4 lines 7-11, it is stated that once "solution aspiration mode" is complete, the plunger is rotated so that the guide pin engages guide track B in "solution dispensing mode". This language is then repeated at column 7 lines 38-5, with further detail. Namely, that the safety shoulder 73 must clear the guide pin 85 so that the plunger can be rotated to align the guide pin 85 with appropriate guide track in dispensing mode.

The first point to be made is that resiliently deformable means “capable of movement (i.e., deformation) in a resilient manner” as indicated by the solid arrow in FIG. 4 of the present application showing that first and second projections 51A, B must be capable of a deformable, lateral movement whereby pawls 42A, 42B of outer member 40 exert an inward pressure on the projections, whereby the projections stop the pawls initially engaging the plunger ratchets (page 5, lines 16-21 and FIG. 5). Following subsequent disengagement of the pawls from the projections, the projections must be sufficiently resilient to “snap back” into a position clear of the plunger and pawls (FIG. 6).

In contrast, the Maffetone guide pin 85 would be incapable of performing this resilient deformable function because the Maffetone guide pin 85 is stationary (see column 3, line 43; column 5 line 22 and line 37; column 7 line 42). That is, it does not move in any way. This is because the plunger is rotated to move the guide pin from guide track A to guide track B.

The second point is that Maffetone would not want the guide pin 85 to be resiliently deformable. If guide pin 85 was resiliently deformable as suggested by the Examiner, it would risk being prematurely dislodged from guide track A before “solution aspiration mode” is complete. This is stated at column 7 lines 38-40 and in FIG. 2 “*Guide pin 85 is shown in abutting contact with safety shoulder 73, thus preventing premature axial rotation of actuating rod 45*”.

Claim 1 and claim 7 recite that “...the inner member comprising one or more projections resiliently deformable to prevent initial engagement of said ratchet by said at least one pawl until said plunger is depressed”. In other words, it is the resilient deformability of the projections that operates to prevent initial engagement of the ratchet by the pawls until plunger depression.

Firstly, applicants submit that a person of ordinary skill in the art would not combine Maffetone and Shaw because the skilled person would not have a reasonable expectation that the guide pin 85 of Maffetone would work sufficiently well in the manner recited by claims 1 and 7.

Secondly, applicants submit that even if the references were combined in the manner suggested by the Examiner, the Maffetone guide pin 85 would not in fact perform the function recited by claims 1 and 7 due to its lack of resilient deformability.

Applicants therefore submit that claims 1-5, 7-11, 13, 16, 18-22 and 24-29 are non-obvious over Shaw in view of Maffetone. Withdrawal of the record rejection and allowance of said claims is respectfully requested.

Claims 6, 14, 15, 23, and 30 stand rejected under 35 U.S.C. 103(a) as being obvious over Shaw and Maffetone in view of UK Patent Application No. GB 2203047 to Banks ("Banks"). This rejection is respectfully traversed.

With regard to claim 6, the Examiner has taken the position that Shaw teaches the device of claim 5, but fails to teach the outer member comprising two fingers and the plunger guide slots. Allegedly, Banks teaches splines that lock into guide channels to prevent rotation of the plunger relative to the body. The Examiner has taken the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Shaw to have guide channels on the handle 116 and splines on the clip 114 as taught by Banks in order to prevent rotation of the plunger with respect to the syringe body (p. 5, lines 1-6).

In response, Applicants again submit that Shaw does not teach all of the limitations of claim 5:

- (i) by failing to teach that the inner member comprises one or more projections which are resiliently deformable to initially prevent engagement of said ratchet by said at least one pawl until said plunger is depressed; and
- (ii) by failing to teach that the inner member and the outer member are in use incapable of rotation relative to each other.

This difference between Shaw and claim 5 is not rectified by the teachings of Maffetone, as hereinbefore argued, or by Banks.

With particular regard to claim 6, this claim recites that the two fingers are on the outer member of the collar, capable of slidably engaging respective, opposed guide slots located on the plunger to thereby prevent rotation of the plunger relative to the collar. Banks teaches the opposite arrangement. Splines 7-10 referred to by the Examiner are on the Banks plunger, not the collar. Likewise, the guide slots 11-14 of Banks relied upon by the Examiner are on the collar, not the plunger. Thus, even if we accept the Examiner's comments (purely for argument's sake) that Shaw, Maffetone and Banks should be combined, Banks teaches the reverse orientation of splines and guide slots to that of claim 6. In other words, the combination

of Shaw and Banks teaches away from the invention of claim 6 by providing a mechanism for preventing plunger rotation that is the reverse of the features required by claim 6. Furthermore, splines 7-10 and collar slots 11-14 in Banks are arranged so that rotation of the plunger can occur after plunger withdrawal is complete (see page 5 lines 14-25 of Banks). The arrangement of claim 6, that the two fingers are on the outer member of the collar capable of slidably engaging respective opposed guide slots located on the plunger, prevents any rotation of the plunger relative to the collar. Therefore, not only does the spline 7-10 and collar slot 11-14 arrangement of Banks have to be reversed, it would also have to be re-engineered to prevent any rotation of the plunger relative to the collar.

Applicants therefore submit that for at least this reason, claim 6 is non-obvious over the combination of Shaw, Maffetone and Banks relied upon by the Examiner.

The above comments are also directly applicable to claims 14, 15, 23 and 30 which each incorporate the features of claim 6 either by claim dependency or by recitation that the two fingers are on the outer member of the collar, capable of slidably engaging respective, opposed guide slots located on the plunger to thereby prevent rotation of said plunger relative to said collar.

Applicants therefore submit that claims 6, 14, 15, 23 and 30 are non-obvious over the combination of Shaw, Maffetone and Banks relied upon by the Examiner for at least the reasons noted above. Withdrawal of the record rejection and allowance of said claims is respectfully requested.

In view of all of the foregoing, Applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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